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## REMARKS

Claims 1-11 and 14-23 were examined. Claims 1, 3, 7, 9, 14, and 17 are amended. Claims 1-11 and 14-23 remain in the Application.

The Patent Office objects to claim 17 and the priority designation of the specification. The Patent Office objects to certain aspects of the specification. With respect to rejections, the Patent Office rejects claims 1,2, 4-8, 10, 11, 14-23 under 35 U.S.C. § 112, first paragraph. The Patent Office rejects claims 14-16, 20, 22 under 35 U.S.C § 102(e) and/or § 103(a). The Patent Office rejects claims 1-11, and 14-23 under 35 U.S.C § 103(a). As per a conversation with the Patent Office on May 21, 2003 reconsideration of the amended claims is requested.

### A. Objection to Claim 17

The Patent Office objects to claim 17 and requests that "such that" be "wherein." Applicants amend claim 17 per the suggestion of the Patent Office with respect to the telephone conference May 21, 2003.

### B. Priority

The Patent Office believes Applicants have not complied with one or more conditions under 35 U.S.C. § 120 to receive a benefit of an earlier filing date (the file date of U.S. Patent No.6,436,446).

Applicants designated the Application as a continuation of U.S. Patent 6,436,446 (application Serial No. 09/365,156), by including a reference to the Parent Application in paragraph [0001]. The inventors on the current application are the same as on the Parent patent.

The application was designated as a continuation, because applicants believe that the subject matter of the claims (1-11 and 14-23) was disclosed in accordance with the requirements of 35 U.S.C. § 112, first paragraph. The applicants have modified the specification by identifying the acid as an *organic* acid as requested by the Patent Office.

For example, a beverage composition including calcium, organic acid and inulin was described in the Parent Patent as was a solid composition, such as a paste or a bar or similar components. In addition, the Applicant overcomes the objection of the Patent Office with respect to all acidifiers and all solubilizers by revising the specification and the claims to incorporate *organic* acid and the claims to encompass specified solubilizers. The Applicant has complied with the Patent Office as per the telephone conversation on May 07, 2003.

**C. 35 U.S.C. § 112 First Paragraph: Rejection of Claims 1,2, 4-8, 10, 11, 14-23**

The Patent Office reject claims 1,2, 4-8, 10, 11, 14-23 under 35 U.S.C. § 112 first paragraph. According to Patent Office, the specification is not enabling for all acidifiers or solubilizers.

**1. Acid/Acidifier**

With respect to a suitable acid, independent claim 1 describes a beverage composition suitable for human consumption comprising effective amounts of, among other components, an acid. The components are together in a soluble composition. Based on the claim language and the Specification, a suitable acid is one that renders the beverage composition (1) soluble, and (2) suitable for human consumption. Applicants believe one of skill in the art can select an acid suitable for human consumption that in the presence of the other components, would render a soluble composition, based on the teachings of the Specification, without undue experimentation. Although, the Applicant believes it is unnecessary to further amend independent claim 1, Applicants do amend to recite "organic" acid in an effort to expedite prosecution.

Independent claim 7 also recites a method including administering a beverage composition suitable for human consumption including, among other solubilized components, an acid. Thus, similar to independent claim 1, Applicants believe a person skilled in the art would be able to select an appropriate acid, given the teachings in the Specification, to be used in a beverage composition suitable for human consumption and allowing the compounds to be solubilized. Although, the Applicant believes it is

unnecessary to further amend independent claim 7, Applicants do amend to recite "organic" acid in an effort to expedite prosecution.

Independent claim 14 relates to a composition that is suitable for human consumption including, among other components, an acidifier. Like the claims noted above, an acidifier must be suitable for human consumption. Applicants believe one of skill in the art would, based on the teachings of the Specification, be able to select an acid for the composition that is suitable for human consumption. Although, the Applicant believes it is unnecessary to further amend independent claim 14, Applicants do amend to recite "organic" acid in an effort to expedite prosecution.

## **2. Stabilizing Agent**

With respect to the stabilizing agent, claim 3 that depends from independent claim 1, recites a stabilizing agent comprising maltol and one of carrageenan and maltodextrin and a xanthan gum. Applicants believe the specification of a stabilizing agent is completely supported by the Specification and no further amendment is needed for one of skill in the art to practice the invention described in the claim. Although, the Applicant believes it is unnecessary to further amend claim 3, Applicants do amend to recite "The method of claim 2, wherein the beverage composition further comprises:a stabilizing agent comprising at least one stabilizer selected from the group consisting of maltol , carrageenan and maltodextrin, and xanthan gum" to expedite prosecution.

Claim 9 that depends from independent claim 7 also describes administering a beverage composition that includes a stabilizing agent. For the reasons stated with respect to claim 3, Applicants believe that one of skill in the art would, given the teachings to the Specification, be able to select an appropriate stabilizing agent. Although, the Applicant believes it is unnecessary to further amend claim 9, Applicants do amend to recite The method of claim 7, wherein the beverage composition further comprises:a stabilizing agent comprising at least one stabilizer selected from the group consisting of maltol , carrageenan and maltodextrin, and xanthan gum" to expedite prosecution.

Claim 17, which depends from claim 14, describes a composition which includes a stabilizing agent. Applicants believe, for the reasons stated above with respect to claim 3, that one of skill in the art would, given the teachings of the Specification be able to select an appropriate stabilizing agent for a composition described. Although, the Applicant believes it is unnecessary to further amend claim 9, Applicants do amend to recite "The method of claim 15, wherein the beverage composition further comprises:a stabilizing agent comprising at least one stabilizer selected from the group consisting of maltol , carrageenan and maltodextrin, and xanthan gum" to expedite prosecution.

Claim 1, 3, 7, 9, 14, and 17 were amended as suggested by the Patent Office. It follows that claims 2,4,5,6,8,10,11,15,16, 18-23 depend from claims 1, 3, 7, 9, 14, and 17 and therefore contain all the limitations of these claims and are considered by the Patent office as per the telephone conversation on May 21, 2003 to be in condition for allowance.

Applicants respectfully request that the Patent Office withdraw the rejection to claims 1,2, 4-8, 10, 11, 14-23 under 35 U.S.C. §112, first paragraph.

D. 35 U.S.C. §102(e)/§103(a): Rejection of Claims 14-16, 20 and 22

The Patent Office rejects claims 14-16, 20 and 22 under 35 U.S.C. § 102(e) as anticipated by, or in the alternative , under 35 U.S.C. § 103(a) as obvious over U.S. Patent No. 6,051, 260 issued to Liska et al. (Liska). The Patent Office direct the Applicant's attention to columns 10 and 11 and claims 7-15 of Liska where a composition that is mixed in water contains inulin, fructooligosaccharides , calcium pantothenate, ascorbic acid, vitamin E, calcium citrate, magnesium citrate, potassium phosphate, vitamin D3 and vitamin K.

Independent claim 14 relates to a composition, including a calcium compound, a magnesium compound, inulin, and a *pH modifying organic acidifier* in an amount up to an equivalent amount of a calcium of a calcium compound. Claim 14 is not anticipated by nor *prima facie* obvious in light of Liska, because Liska fails to describe an acidifier in an amount up to an equivalent amount of a calcium of a calcium compound. Liska discloses a source of pantothenic acid and folic acid that are dietary supplement sources and of which

neither are described as acidifiers. Further, there is no teaching or motivation in Liska to add an acidifier in the composition of Liska. In addition, Liska fails to describe a pH range of pH 3 to pH 5 as described herein.

Applicant respectfully request the Patent Office withdrawl the rejection of independent claim 14 under 35 U.S.C. §102(e) or §103(a). Claims 15, 16, 20 and 22 depend from claim 14 and therefore contain all the limitations of that claim. Claims 14-16, 20 and 22 are not anticipated by or obvious over Liska for at least the reasons described above.

Applicant respectfully requests the Patent Office withdrawl the rejection to claims 14-16, 20 and 22 under 35 U.S.C. §102(e) or §103(a).

#### E. 35 U.S.C. §103(a): Rejection of Claims 1-11, 14-23

The Patent Office rejects claims 1-11, 14-23 under 35 U.S.C. §103(a) as obvious over Liska in view of U.S. Patent No. 5,900,255 issued to Ohta et al. (Ohta) in view of European Patent Application No. WO99/07392 of Otsuka Pharmaceutical Co., Ltd. (Otsuka), "Improvement of Calcium Absorption" by Orafti (Orafti), U.S. Patent No. 6,171,633 issued to Dulebohn et al. (Dulebohn), and U.S. Patent No. 6,150,399 issued to Patel et al. (Patel) and U.S. Patent No. 5,128,374 issued to Kochanowski (Kochanowski).

Liska is cited as before for teaching a composition that can be mixed in water or fruit juice containing inulin, fructooligosaccharides, calcium and magnesium. As noted above, Liska does not describe a relationship between an *organic* acid or pH modifying acid component and the calcium component or the solubility of a beverage composition.

Ohta describes a composition comprising calcium, magnesium, and fructooligosaccharides. The composition can be in a liquid form, however, no detail is given as to whether such material would be soluble in the liquid. Ohta also does not describe an *organic* acid or acidifier in relation to a calcium component and solubility of calcium. The examples given for application include biscuits (Example 2), chocolates (Example 3), and candies (Example 4).

Orafti describes the experimental observation of calcium and magnesium by inulin-

type fructons. Orafti does not describe a solubilized calcium beverage or a relationship between an *organic* acid or acidifier and a calcium component. Orafti also fails to mention inulin, a component herein that increases calcium absorption.

Dulebohn describes a milk/juice combination with a gum-based stabilizer and a composition including an amino acid, an acid, a metal and stabilize the composition for up to one year. One example of the stabilizing composition is 4.69 moles MgO; 2.72 moles malic acid; and 3.41 moles citric acid. From these examples, the amount of acid is 6.13 moles. There is no example where a calcium composition is present in that amount. Also, Dulebohn fails to mention inulin included in independent claims 1 and 14, a component herein that increases calcium absorbability.

Patel describes a soy protein/isoflavone nutritional composition. Patel uses a carbohydrate system including maltodextrin, corn syrup and sucrose to optimize the mouth feel of the product. Carrageenans may also be included to improve the suspension of insoluble minerals, product stability and mouth feel. Patel does not describe a relationship between a calcium component and an *organic* acid component. The liquid beverage also does not, from Applicants' understanding, appear to be a solubilized calcium beverage. Also, Patel fails to mention inulin included in independent claims 1 and 14, a component herein that increases calcium absorbability

Kochanowski describes a calcium compound that can be solubilized by mixing calcium salt and citric acid and malic acid, in a ratio; a preferred ratio is 1:0.7 to 1:0.9. Kochanowski does not describe a relationship between the solubility and a specified pH range. Kochanowski fails to indicate that a pH modifying organic acid is required for increased calcium solubility. Kochanowski fails to indicate inulin included in independent claims 1 and 14, a component herein that increases calcium absorbability

Independent claim 1 is *prima facie* not obvious over the cited references, because the cited references fail to describe a method including administering a beverage composition of solubilized components at a pH 3 to pH 5 and an organic acid in the beverage is present in an amount of up to the equivalent amount of a calcium in the beverage composition. Liska, Ohta and Otsuka each describes drinks with collectively, calcium, inulin, and

fructooligosaccharides, but do not describe the component solubilized in the drink.

Dulebohn and Patel describe beverage compositions including isoflavones, calcium, acid, but do not describe inulin or the relationship between a calcium component and the organic acid component. Kochanowski describes beverage and solid compositions of calcium and malate/citrate but do not describe the required pH range or the inulin component. Further, it is not clear that Dulebohn and Patel disclose a solubilized composition.

From the cited references, there is no motivation for the method described by independent claim 1. Representatively, it is generally known that calcium is difficult to solubilize. See U.S. Patent No. 5,401,524 issued to Burkes et al. (Burkes) and U.S. Patent No. 5,389,387 issued to Zuniga et al. (Zuniga). Therefore, it cannot be assumed that the references cited by the Patent office will produce a solubilized component absent, for example, some teaching of how solubilization is achieved, such as the relationship of the *organic* acid component. Furthermore, as indicated in the application, a specific pH range is required for stability and increased solubility as well as in some situations for example an inulin component for increased absorbability.

For the above stated reasons, independent claim 1 is not obvious over the cited references. Claims 2-6 depend from claim 1 and therefore contain all the limitations of claim 1. For at least the reasons stated above with respect to claim 1, claims 2-6 are not obvious over the cited reference.

Independent claim 7 related to a method including administering a beverage composition having solubilized components of calcium, magnesium, a pH modifying organic acid, and fructo-oligosaccharide. Claim 7 is *prima facie* not obvious over the cited references because the references fail to describe a composition of solubilized component or an organic acid present in an amount up to the equivalent amount of a calcium of the calcium compound. In addition, Kochanowski fails to describe a specific pH range or a fructo-oligosaccharide component. For the reasons stated with respect to independent claim 1, there is also no motivation from the cited references for administering a solubilized beverage composition of a specified pH range as claimed.

For the reasons stated above, independent claim 7 is not obvious over the cited references. Claim 8-11 depend from claim 7 and therefore contain all the limitations of claim 7. For the reasons stated with respect to claim 7, claims 8-11 are not obvious over the cited references.

Independent claim 14 relates to a composition including calcium, magnesium, inulin and an *organic* acidifier in an amount up to the equivalent amount of a calcium of a calcium compound. The composition, when combined in solution is a translucent composition. Claim 14 is *prima facie* not obvious over the cited references, because the cited references fail to disclose a composition including an organic acidifier in an amount up to the equivalent amount of a calcium of a calcium compound in a composition, or a composition that may be translucent when combined in solution. In addition, Kochanowski fails to describe a specific pH range or an inulin component. For the reasons stated above with respect to independent claim 1, there is also no motivation from the cited references for administering a solubilized beverage composition of a specified pH range as claimed in the composition of claim 14.

For the above-stated reasons, claim 14 is not obvious over the cited references. Claims 15-23 depend from claim 14 and therefore contain all the limitations of claim 14. For at least the reasons stated above with respect to claim 14, claims 15-23 are not obvious over the cited references.

Applicants respectfully request that the rejection under 35 U.S.C § 103(a) be withdrawn.

#### F. Double Patenting

The Patent Office rejects claim 1-11, 14-23 under the judicially created doctrine of obviousness-type double patenting over U.S. Patent No. 6,436,446 ( previously Application No. 09/365,156). Applicants have previously submitted a terminal disclaimer recognized and accepted by the Patent Office per telephone conversation May 07, 2003. Applicants respectfully request that the Patent Office withdraw the double patenting rejection to claims 1-11, 14-23

Attached hereto is a marked-up version of the changes made to the specification and claims by the current amendments. The attached page is captioned "Version with Markings to Show Changes Made"

## **CONCLUSIONS**

Applicants respectfully submit that the rejections have been overcome by the amendments and remarks, and that the claims as amended are now in condition for allowance. Accordingly, Applicants respectfully request the rejections be withdrawn and the claims as amended be allowed.

### **Invitation for a Telephone Interview**

The Examiner is requested to call the undersigned at (303) 740-1980 if there remains any issue with allowance of the case.

Respectfully submitted,

BLAKELY, SOKOLOFF, TAYLOR & ZAFMAN LLP

Date: May 30, 2003

  
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**Version with Markings to Show Changes Made**

**Insertions are underlined, deletions are bracketed.**

**IN THE SPECIFICATION**

Please amend the Specification as follows:

[0011] In one aspect of a beverage form, the composition maximizes the solubility of the components by, in one embodiment, including a stabilizing agent of at least one of maltol, a composition of carrageenan and maltodextrin, or xanthan gum. The beverage composition may be a clear or a colored solution without significant residue or sediment (e.g., generally translucent). The beverage is also, preferably, adjusted to a pH between 3 and 7 and more preferably between pH 4 and 5 at room temperature with an organic acidifier in an amount up to the equivalent amount of a calcium of the calcium compound in the composition.

[0032] In one embodiment of a beverage composition wherein the individual components of the composition are soluble (e.g., a generally translucent beverage), the organic acidifier is present in an amount up to the equivalent amount of a calcium component. Examples 1 through 7 described herein present embodiments where the amount of calcium  $(0.05/240)(100)$  and the amount of acidifier  $((0.336 \text{ citric acid} + 0.172 \text{ malic acid})/240)(100)$  are each 0.21 percent.

**IN THE CLAIMS**

1. (Currently Amended) A method comprising:  
administering a beverage composition suitable for human consumption comprising effective amounts of the following solubilized components:  
a calcium compound;  
a pH modifying organic acid in an amount up to the equivalent amount of a calcium of the calcium compound wherein the final pH range is between pH 3 and pH 5; and

inulin,

wherein the effective amounts are sufficient to reduce the risk of bone density loss.

2. (Original) The method of claim 1, wherein the composition further comprises amounts of Vitamin D<sub>3</sub> and Vitamin K.

3. (Currently Amended) The method of claim 2, wherein the beverage composition further comprises:

a stabilizing agent comprising at least one stabilizer selected from the group consisting of maltol, carrageenan and maltodextrin, and xanthan gum.

4. (Original) The method of claim 3, wherein the effective amounts of the individual components are selected for an individual serving size representing a portion less than a daily predetermined amount.

5. (Original) The method of claim 1, wherein the composition further comprises effective amounts of a magnesium compound.

6. (Previously Amended) The method of claim 1, wherein the composition further comprises an isoflavone.

7. (Currently Amended) A method comprising:

administering a beverage composition suitable for human consumption comprising amounts of the following solubilized compounds:

a calcium compound;

a magnesium compound;

a pH modifying organic acid in an amount up to the equivalent amount of a calcium of the calcium compound wherein the final pH range is between pH 3 and pH 5; and;

a fructo-oligosaccharide.

8. (Original) The method of claim 7, wherein the composition further comprises Vitamin D<sub>3</sub>.

9. (Currently Amended) The method of claim 7, wherein the beverage composition further comprises:

a stabilizing agent comprising at least one stabilizer selected from the group consisting of maltol, carrageenan and maltodextrin, and xanthan gum.

10. (Original) The method of claim 7, wherein the effective amounts of the individual components are selected for an individual serving size representing a portion less than a daily predetermined amount.

11. (Original) The method of claim 7, wherein the composition further comprises an isoflavone.

14. (Currently Amended) A composition suitable for human consumption comprising a portion of a daily amount of:

a dietary acceptable calcium compound;

a dietary acceptable magnesium compound;

a dietary acceptable inulin; and

a pH modifying organic acid in an amount up to the equivalent amount of a calcium of the calcium compound wherein the final pH range is less than pH 5; and,

wherein, when combined in solution, the composition is translucent.

15. (Original) The composition of claim 14, further comprising:

a dietary acceptable Vitamin D<sub>3</sub>; and

a dietary acceptable Vitamin K.

16. (Previously Amended) The composition of claim 15, wherein the composition is one of a ready-to-drink solubilized beverage and a soluble beverage preparation.

17. (Currently Amended) The composition of claim 15, wherein the composition is a beverage and further comprising:

a stabilizing agent comprising at least one stabilizer selected from the group consisting of maltol, carrageenan and maltodextrin, and xanthan gum, [such that] wherein each component of the composition is soluble in the liquid.

18. (Original) The composition of claim 17, further comprising a dietary acceptable isoflavone .

19. (Original) The composition of claim 18, wherein the isoflavone is a soy isoflavone that comprises at least one of a daidzein compound, a genistein compound, and a glycitein compound.

20. (Original) The composition of claim 14, wherein the weight ratio of calcium to magnesium is in the range of five to one and three to one.

21. (Original) The composition of claim 18, wherein the weight ratio of calcium to isoflavones is in the range of ten to one.

22. (Original) The composition of claim 14, wherein the weight ratio of calcium to inulin is one to ten.

23. (Previously Amended) The composition of claim 14, wherein the magnesium compound further comprises phosphorus.